

## DOCUMENT INFORMATION PAGE

This page is for FDA internal use only. Do **NOT** send this page with the letter.

<b>Application #(s):</b>	NDA 219293/S-006
<b>Communication Type:</b>	Correspondence
<b>Communication Group:</b>	sNDA Action
<b>Communication Name:</b>	Approval
<b>Communication ID:</b>	COR-SNDAACTION-05
<b>Drafted by:</b>	ABaird 4/13/2026; KNorsworthy 4/13/2026; CRabik 4/14/2026
<b>Clearance History by:</b>	
<b>Finalized:</b>	ABaird 4-14-2026
<b>Filename:</b>	
<b>Signatory Authority:</b>	<b>For Efficacy Supplements or Labeling Supplements:</b> OND Division Director or Deputy Division Director. Person who is covering for the signatory authority can sign on their behalf (i.e., the signature block on the letter will not change) <b>For CMC Supplements with Labeling:</b> OPQ Division Director or Branch Chief
<b>Use Statement:</b>	Use to notify applicant of an approval action for a supplemental application that includes changes to the label(s) and/or labeling
<b>Notes:</b>	USE "sNDA Approval [OTC ONLY]" template for Over-the-Counter sNDA Approvals USE COR-SNDAACTION-06 FOR sNDA CMC APPROVALS USE COR-SNDAACTION-09 FOR sNDA TENTATIVE APPROVALS  If supplement approval also fulfills a PMR/PMC, this letter will need to be double-coded as PMR-PMC Fulfilled.  <b>Note:</b> Remember to check for acceptability of facility <b><u>prior to issuing approval letter.</u></b>  <b>Labeling:</b> Before attaching labeling, ensure that the following items have been addressed (see "Final Check of Labeling Format Before Attaching Documents to Approval Letter" slide presentation on <a href="#">CDER Prescription Drug Labeling Resources website</a> for details):

- 1) Remove annotations (e.g., tracked changes, comments, content in headers/footers); however, page numbers are allowed (see #5)
- 2) Remove line numbers
- 3) Assess number of columns in three sections of labeling (two columns for Highlights and Table of Contents, and one-column for Full Prescribing Information). If incorrect, ask applicant to address.
- 4) Correct/update dates in Highlights (e.g., Initial U.S. Approval, Recent Major Changes, and Revision Date)
- 5) If page numbers are included, ensure first page of each labeling document starts with Page #1 (e.g. Prescribing Information, Patient Package Insert, Medication Guide, and Instructions for Use all start with Page #1)

Version: 02/09/2026

**END OF DOCUMENT INFORMATION PAGE**

**The letter begins on the next page.**

NDA 219293/S-006

## **SUPPLEMENT APPROVAL**

Azurity Pharmaceuticals, Inc.  
Attention: Justin Kilby  
Associate Director, Regulatory Affairs  
8 Cabot Road, Suite 2000  
Woburn, MA 01801

Dear Justin Kilby:

Please refer to your supplemental new drug application (sNDA) dated October 15, 2025, received October 15, 2025, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for DANZITEN (nilotinib) tablets.

This Prior Approval sNDA provides for updates to the United States Prescribing Information (USPI) regarding the cutting, crushing or chewing of tablets for patients with swallowing difficulties.

### **APPROVAL & LABELING**

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.<sup>1</sup> Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Medication Guide), with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.<sup>2</sup>

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

<sup>2</sup> We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

### **CARTON AND CONTAINER LABELING**

Submit final printed carton and container labeling that are identical to the carton and container labeling submitted on April 2, 2026, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Final Printed Carton and Container Labeling for approved NDA 219293/S-006.**” Approval of this submission by FDA is not required before the labeling is used.

### **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your supplemental application, you are exempt from this requirement.

### **PATENT LISTING REQUIREMENTS**

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book

are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

### **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, contact Tawanna Stokes, Regulatory Information Specialist, at 796-2927 or via e-mail to [tawanna.stokes@fda.hhs.gov](mailto:tawanna.stokes@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Kelly Norsworthy, MD  
Division Director  
Division of Hematologic Malignancies I  
Office of Oncologic Diseases  
Center for Drug Evaluation and Research

#### ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide